NON-TECHNICAL ABSTRACT

The purpose of this research is to develop a new and powerful type of immune therapy for patients with metastatic renal cell carcinoma. It is believed that the body's immune system can attack tumor cells and kill them. This is thought to be due to immune cells called T lymphocytes (T cells), which can recognize special proteins on the surface of tumor cells as a signal to fight the cancer. In most patients with advanced cancer, though, the immune system does not adequately destroy the tumor because the T cells are not stimulated sufficiently. T cells require strong stimulation before they grow and become active against tumor cells. There are special "stimulator" cells in the body called dendritic cells, which can take up proteins released from cancer cells and present pieces of these proteins to T lymphocytes to create a strong stimulatory signal. In addition to proteins, substances called ribonucleic acids (RNA) carry the genetic instructions for the production of proteins and can be used to stimulate an immune response. The advantage of using RNA is that it may be stronger than the proteins in stimulating an immune response. Recent studies have shown that a medicine called denileukin difitox (Ontak®) may increase an immune response. We hypothesize that pretreatment with the recombinant IL2-diphteria toxin conjugate denileukin difitox (ONTAK®) will augment the immune response of mature, renal tumor RNA transfected dendritic cells, when compared to patients receiving renal tumor RNA transfected dendritic cells alone.
In order to test this, we have designed a clinical study and will enroll patients with metastatic renal cancer to look at these two forms of therapy and compare which therapy is best in stimulating the immune system against cancer.

The main objectives of this study are:

a) To evaluate the safety of administering injections of dendritic cells grown from blood cells and mixed together for a short period of time with the patient's own tumor.
b) To evaluate the safety of administering ONTAK® followed by injections of dendritic cells grown from blood cells and mixed together for a short period of time with the patient's own tumor.
c) To determine which form of therapy stimulates the immune system best.
d) To monitor whether or not tumor shrinkage based on X-ray studies will occur.

We hope that this new form of immune therapy, although in its infancy, will ultimately slow down tumor growth and prolong survival of patients with renal cancer.